WHAT IS CLAIMED IS:

1. A method of determining the efficacy of a treatment of inflammatory diseases of the bowel in mammals *in vivo* comprising the steps of:

a) measuring the level of at least one anti-inflammatory cytokine and at least one pro-inflammatory cytokine in a biological sample from a mammalian subject;

b) determining the ratio of the at least one anti-inflammatory cytokine to the at least one pro-inflammatory cytokine;

c) administering said treatment;

d) measuring the level of the at least one anti-inflammatory cytokine and the at least one pro-inflammatory cytokine in a biological sample from said mammalian subject at a time following administration of said treatment;

e) determining the ratio of the at least one anti-inflammatory cytokine to the at least one pro-inflammatory cytokine following administration of said treatment;

wherein an increase in the ratio of anti-inflammatory cytokine to pro- inflammatory cytokine following the administration of said treatment is indicative of an inhibitor of inflammatory diseases of the bowel, and no change or a decrease in the ratio of anti-inflammatory cytokine to pro-inflammatory cytokine following the administration of said treatment is indicative said treatment not being an inhibitor of inflammatory diseases of the bowel.

2. The method according to claim 1 wherein the anti-inflammatory cytokine is selected from the group comprising interleukin-10, transforming growth factor-β, interleukin-4, interleukin-5, interleukin-13, and mixtures thereof.

3. The method according to claim 2 wherein the anti-inflammatory cytokine is selected from the group comprising interleukin-10, transforming growth factor-β, and mixtures thereof.

4. The method according to claim 1 wherein the pro-inflammatory cytokine comprises interleukin-12, tumour necrosis factor-α, interferon-γ, interleukin-2, and mixtures thereof.

5. The method according to claim 4 wherein the pro-inflammatory cytokine comprises interleukin-12, tumour necrosis factor-α, interferon-γ, and mixtures thereof.

6. The method according to claim 1, wherein said ratio of anti-inflammatory cytokine to pro-inflammatory cytokine is the ratio interleukin-10/interleukin-12.

7. The method according to claim 1, wherein said ratio of anti-inflammatory cytokine to pro-inflammatory cytokine is the ratio transforming growth factor-β/interleukin-12.

8. The method according to claim 1, wherein said ratio of anti-inflammatory cytokine to pro-inflammatory cytokine is the ratio interleukin-10/interferon-γ.

9. The method according to claim 1 wherein said biological sample comprises urine, plasma, serum, saliva, tissue biopsies, cerebrospinal fluid, peripheral blood mononuclear cells with *in*

vitro stimulation, peripheral blood mononuclear cells without *in vitro* stimulation, gut lymphoid tissues with *in vitro* stimulation, gut lymphoid tissues without *in vitro* stimulation, gut lavage fluids, and mixtures thereof.

10. The method according to claim 9 wherein said biological sample comprises serum, peripheral blood mononuclear cells with *in vitro* stimulation, peripheral blood mononuclear cells without *in vitro* stimulation, and mixtures thereof.

11. The method according to claim 10 wherein said biological sample comprises peripheral blood mononuclear cells with *in vitro* stimulation, peripheral blood mononuclear cells without *in vitro* stimulation, and mixtures thereof.

12. The method according to claim 9 wherein said *in vitro* stimulation comprises a mitogen, probiotic, anti-CD3 molecule, and mixtures thereof.

13. The method according to claim 10, wherein said *in vitro* stimulation comprises a mitogen.

14. The method according to claim 13 wherein said mitogen comprises a lipopolysaccharide, lectin, superantigen, and mixture thereof.

15. The method according to claim 14, wherein said lectin comprises concanavalin A, phytohemagglutinin, pokeweed mitogen, and mixtures thereof.

16. The method according to claim 1 wherein the means for measuring the levels of said at least one anti-inflammatory cytokine in said biological sample comprises ELISAs, radioimmunoassays, multiplexed ELISAs on microarray platforms, multiplexed ELISAs using coded microspheres coupled with a flow cytometer detection systems, bioassays, Western blots, chromatograph-based separation systems, RT-PCR, competitive reverse transcription PCR, Northern blots, gene arrays, direct measurement of m-RNA, and mixtures thereof.

17. The method according to claim 16 wherein the means for measuring the levels of anti-inflammatory cytokines in said biological sample comprises ELISAs, RIAs, multiplexed ELISAs using coded microspheres coupled with a flow cytometer detection systems, and mixtures thereof.

18. The method according to claim 17 wherein the means for measuring the levels of said at least one anti-inflammatory cytokine in said biological sample comprises multiplexed ELISAs using coded microspheres coupled with a flow cytometer detection systems.

19. The method according to claim 1 wherein the means for measuring the levels of said at least one pro-inflammatory cytokine in said biological sample comprises ELISAs, radioimmunoassays, multiplexed ELISAs on microarray platforms, multiplexed ELISAs using coded microspheres coupled with a flow cytometer detection systems, bioassays, Western blots, chromatograph-based separation systems, RT-PCR, competitive reverse transcription PCR, Northern blots, gene arrays, direct measurement of m-RNA, and mixtures thereof.

20. The method according to claim 19 wherein the means for measuring the levels of said at least one pro-inflammatory cytokine in said biological sample comprises ELISAs, RIAs, multiplexed ELISAs using coded microspheres coupled with a flow cytometer detection systems, and mixtures thereof.

21. The method according to claim 20, wherein the means for measuring the levels of said at least one pro-inflammatory cytokine in said biological sample comprises multiplexed ELISAs using coded microspheres coupled with a flow cytometer detection systems.

22. A kit comprising a first measuring element or system for measuring at least one anti-inflammatory cytokine in a biological sample from a mammalian subject before treatment and at at least one time point after or during treatment, a second measuring element or system for measuring at least one pro-inflammatory cytokine in a biological sample from said mammalian subject before treatment, and at at least one time point after or during treatment, wherein the change in ratio of anti-inflammatory to pro-inflammatory cytokine after administration of the treatment can be determined and usage instructions directing the user to determine the ratio of an anti-inflammatory cytokine to a pro-inflammatory cytokine both before and after treatment, and that an increase in said ratio of anti-inflammatory cytokine to said pro-inflammatory cytokine is indicative of an inhibitor of inflammatory diseases of the bowel.

23. The kit according to claim 22, wherein said kit further comprises means for obtaining said biological samples before and after treatment.

24. An *in vitro* method of screening compositions for efficacy in the treatment of inflammatory diseases of the bowel comprising the steps of:

e) providing a biological sample comprising at least one gut-derived cell type;

f) treating said biological sample with the composition *in vitro*;

g) measuring the level of at least one anti-inflammatory cytokine and at least one pro-inflammatory cytokine in the biological sample at a time following treatment with the composition;

h) determining the ratio of the at least one anti-inflammatory cytokine to the at least one pro-inflammatory cytokine in the biological sample at a time following treatment with the composition;

characterised in that a ratio as determined in step (d) from the treated biological sample greater than the same ratio determined in an untreated control biological sample tested concurrently is indicative of the composition being an inhibitor of inflammatory diseases of the bowel, and a ratio as determined in (d) is the same as or less than the untreated control biological sample ratio is indicative of the composition not being an inhibitor of inflammatory diseases of the bowel.

25. The method of claim 24 wherein the biological sample comprises gut-associated lymphoid tissue.
26. The method of claim 25 wherein the gut-associated lymphoid tissue comprises mesenteric lymph node cells.
27. The method according to claims 24 comprising the additional step of stimulating the biological sample *in vitro* prior to step (c).
28. The method according to claim 24 wherein the anti-inflammatory cytokine is selected from the group comprising interleukin-10, transforming growth factor-β, interleukin-4, interleukin-5, interleukin-13, and mixtures thereof.
29. The method according to claim 28 wherein the anti-inflammatory cytokine is selected from the group comprising interleukin-10, transforming growth factor-β, and mixtures thereof.
30. The method according to claim 24 wherein the pro-inflammatory cytokine comprises interleukin-12, tumour necrosis factor-α, interferon-γ, interleukin-2, and mixtures thereof.
31. The method according to claim 30 wherein the pro-inflammatory cytokine comprises interleukin-12, tumour necrosis factor-α, interferon-γ, and mixtures thereof.
32. The method according to claim 24, wherein said ratio of anti-inflammatory cytokine to pro-inflammatory cytokine is the ratio interleukin-10/interleukin-12.
33. The method according to claim 24, wherein said ratio of anti-inflammatory cytokine to pro-inflammatory cytokine is the ratio transforming growth factor-β/interleukin-12.
34. The method according to claim 24, wherein said ratio of anti-inflammatory cytokine to pro-inflammatory cytokine is the ratio interleukin-10/interferon-γ.
35. The method according to claim 27 wherein said *in vitro* stimulation comprises a mitogen, probiotic, anti-CD3 molecule, and mixtures thereof.
36. The method according to claim 35, wherein said *in vitro* stimulation comprises a mitogen.
37. The method according to claim 36 wherein said mitogen comprises a lipopolysaccharide, lectin, superantigen, and mixture thereof.
38. The method according to claim 37, wherein said lectin comprises concanavalin A, phytohemagglutinin, pokeweed mitogen, and mixtures thereof.
39. The method according to claim 24 wherein the means for measuring the levels of said at least one anti-inflammatory cytokine in said biological sample comprises ELISAs, radioimmunoassays, multiplexed ELISAs on microarray platforms, multiplexed ELISAs using coded microspheres coupled with a flow cytometer detection systems, bioassays, Western blots, chromatograph-based separation systems, RT-PCR, competitive reverse

transcription PCR, Northern blots, gene arrays, direct measurement of m-RNA, and mixtures thereof.

40. The method according to claim 39 wherein the means for measuring the levels of anti-inflammatory cytokines in said biological sample comprises ELISAs, RIAs, multiplexed ELISAs using coded microspheres coupled with a flow cytometer detection systems, and mixtures thereof.

41. The method according to claim 40 wherein the means for measuring the levels of said at least one anti-inflammatory cytokine in said biological sample comprises multiplexed ELISAs using coded microspheres coupled with a flow cytometer detection systems.

42. The method according to claim 41 wherein the means for measuring the levels of said at least one pro-inflammatory cytokine in said biological sample comprises ELISAs, radioimmunoassays, multiplexed ELISAs on microarray platforms, multiplexed ELISAs using coded microspheres coupled with a flow cytometer detection systems, bioassays, Western blots, chromatograph-based separation systems, RT-PCR, competitive reverse transcription PCR, Northern blots, gene arrays, direct measurement of m-RNA, and mixtures thereof.

43. The method according to claim 42 wherein the means for measuring the levels of said at least one pro-inflammatory cytokine in said biological sample comprises ELISAs, RIAs, multiplexed ELISAs using coded microspheres coupled with a flow cytometer detection systems, and mixtures thereof.

44. The method according to claim 43, wherein the means for measuring the levels of said at least one pro-inflammatory cytokine in said biological sample comprises multiplexed ELISAs using coded microspheres coupled with a flow cytometer detection systems.

45. A kit for screening compositions for efficacy in the treatment of inflammatory diseases of the bowel comprising a first measuring element or system for measuring at least one anti-inflammatory cytokine in a biological sample comprising a gut-derived cell type, a second measuring element or system for measuring at least one pro-inflammatory cytokine in a biological sample comprising a gut-derived cell type, wherein the difference in ratio of anti-inflammatory to pro-inflammatory cytokine between a control sample and a treated sample that has been stimulated with a composition can be determined, and usage instructions directing the user to determine the ratio of an anti-inflammatory cytokine to a pro-inflammatory cytokine, and that a ratio of anti-inflammatory cytokine to said pro-inflammatory cytokine greater than the control is indicative of an inhibitor of inflammatory diseases of the bowel.